

### **Remarks**

This is in response to the Office Action dated December 12, 2006.

Claims 1 and 9 have been rejected under 35 USC 102 (b) as being anticipated by Arkinstall (US5287852); claims 2-6 and 8 have been rejected under 35 USC 103(a) as being obvious over the combination of Arkinstall and McCoy (US6848242); and claim 7 has been rejected as being obvious over the Arkinstall/McCoy combination and further in view of Augustine (US5638813).

Per the above amendment, claim 2 has been amended to incorporate therein the subject matter of claim 2, namely that the device includes a seal that seals the trachea above the opening into the trachea. Further, the phrase "against the flow of gas" has been added after "trachea" to make it clear that the inventive "seal" is a gas seal, not simply a trap for secretions.

Arkinstall (US5287852) describes a tracheal stoma device that extends through the neck and terminates just inside the trachea, being sealed in the trachea by an inflatable ring.

Against canceled Claim 2, the Examiner has cited McCoy (US6840242), which shows a substantially conventional tracheostomy tube and a collection receptacle above the tube to collect secretions produced in the upper part of the trachea. The difference, therefore, with McCoy is that the inventive device uses a cuff on the tracheostomy tube to provide a seal against the flow of gas along the trachea. There is no suggestion by McCoy that his collection receptacle be arranged to seal against the flow of gas, instead, it is used exclusively for collecting secretions (column 2, lines 60-69).

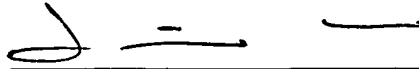
It should be noted that the device proposed by Arkinstall is intended primarily for patients who are being weaned off ventilation and is, therefore, intended to permit gas flow

along the full length of the trachea and out/in via the mouth or nose, as well as some gas flowing in and out via the tracheostomy (column 1, lines 38-42; column 7, lines 49-54). When ventilation is required (and hence a gas seal must be produced in the trachea), such as if the patient's health deteriorates, Arkinstall teaches that a separate, conventional tracheostomy tube be inserted via the stoma device (Figure 3; column 7, lines 25-27). Such a tube is provided with an inflatable cuff at its patient end to form the gas seal. Thus, Arkinstall certainly does not contemplate that a short tracheostomy tube terminating at the inner surface of the trachea could itself be used for ventilating a patient, in the manner possible with the arrangement of the present invention.

The examiner has asserted that it would have been obvious to modify the device of Arkinstall to include the seal of McCoy "in order to collect secretions that accumulate so that it does not interfere with the tracheostomy device and opening as taught by McCoy (column 3, lines 1-21)." [Page 4 of the Office Action] Yet as noted above, the Arkinstall device is intended primarily for patients who are being weaned from ventilation. Indeed, Arkinstall discloses that should secretions accumulate in the trachea, a conventional catheter is inserted through his device to extend down to the trachea in order to withdraw secretions from the trachea (column 7, lines 42-48). Thus, there is no suggestion in Arkinstall that his device should be modified as suggested by the examiner insofar as Arkinstall specifically teaches how to remove secretions. Further, given that the device of Arkinstall could be sealed, when the patient has successfully weaned from the ventilator, by a plug, per shown in Fig. 5 (column 7, lines 49-54), by modifying the Arkinstall device per suggestion by the examiner would cut off the air passage to the patient. Thus, it is respectfully submitted that McCoy and Arkinstall may not be combined as suggested by the examiner.

In view of the foregoing, it is respectfully submitted that the instant invention is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,



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